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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,085	05/03/2006	Shinji Okano	50026/058001	5137

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)
	10/578,085	OKANO ET AL.
	Examiner	Art Unit
	QUANG NGUYEN	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5-7,10,15,20,25 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-7,10,15,20,25 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/11;2/9/11;12/15/10;12/6/10;8/20/10*.	6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/11 has been entered.

Amended claims 2, 5-7, 10, 15, 20, 25, 30-34 are pending in the present application.

Response to Amendment

The rejection under 35 U.S.C. 102(b) as being anticipated by Gary-Gouy et al (J. Interferon and Cytokine Res. 22:653-659, 2002; IDS) was withdrawn in light of Applicant's amendment, particularly the limitation "a Sendai virus vector of a Sendai virus Z strain".

The rejection under 35 U.S.C. 102(e) as being anticipated by Pickles et al (US 2005/0048030; IDS) was withdrawn in light of Applicant's amendment, particularly the limitation "a Sendai virus vector of a Sendai virus Z strain".

Information Disclosure Statement

All of the documents listed in the information disclosure statements (IDS) submitted on 8/20/10; 12/6/10; 12/15/10; 2/9/11 and 6/29/11 have been considered by

the examiner. However, certain documents were crossed out because they are not proper references to be printed on the first page of an issued US patent.

Specification

The specification is objected because it lacks antecedent for the term “Z strain” that is recited in the claims.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5, 10, 20, 25 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***This is a new ground of rejection.***

Independent claim 2 recites the new limitation **"A method for producing a mature dendritic cell….contacting a Sendai virus vector of a Sendai virus Z strain”.** The instant claims are drawn to a method for producing a mature dendritic cell comprising the step of contacting a Sendai virus vector of a Sendai virus Z strain, encompassing the use of a wild-type Sendai virus Z strain and/or a recombinant Sendai virus Z strain containing a heterologous gene. The as-filed specification does not have

a written support for a method of producing a mature dendritic cell as now claimed broadly. In the amendment filed on 1/10/2011 (pages 5-6), Applicants cited certain pages in the present application as alleged written supports for the currently amended claims. However, it is noted that none of these cited pages teaches specifically the specific concept of using **a wild type Sendai virus vector of a Sendai virus Z strain without any heterologous transgene for producing a mature dendritic cell as encompassed by the instant claims**. The title of the instant application "Method of constructing transgenic dendritic cell", original claims and all the exemplifications do not support the concept of using a wild type Sendai virus strain Z for the production of a mature dendritic cell. Applicants are invited to point out the specific page and line numbers that support for such an embodiment.

Therefore, given the lack of guidance provided by the originally filed specification as discussed above, it would appear that **Applicants did not specifically contemplate or have possession of the instant broadly claimed invention at the time the application was filed**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 2, 5-7, 10, 15, 20, 25, 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al. (US 2002/0123479 A1) in view of Tokusumi et al. (US 6,746,860; IDS), Jin et al. (Gene therapy 10:272-277, February 2003; IDS), Hwu et al (US 6,734,014) and Waller et al (US 2005/0013810). ***This is a modified rejection.***

Song et al disclose compositions and methods useful for stimulating an immune response against one or more disease associated antigens, including cancer associated antigens, by **genetically modifying dendritic cells including dendritic progenitor cells as well as dendritic cells having CD11c+ maker, *in vivo* or *ex vivo*, wherein the dendritic cells were genetically modified by a recombinant negative strand RNA virus (e.g., vesicular stomatitis virus, paramyxoviruses, orthomyxoviruse and bunyaviruses) directing the expression of at least one disease associated antigen** (see at least Summary of the Invention; particularly paragraphs 6-7, 9-12, 16-18, 41-45, 60 and Figure 1). Since the starting dendritic cells (including both dendritic

cells and dendritic progenitors) used by Song et al do not express markers such as CD80, CD83 and CD86 (see at least Figure 1 for cellular dendritic cell markers taught by Song et al; paragraphs 9, 41-44), they fall within the scope of "immature dendritic cells" as defined by the present application (see at least page 10, lines 16-20; page 11, lines 14-19). It is further noted that the transfected dendritic cells were not further subjected to any additionally treatment such as LPS stimulation for high expression of matured dendritic cell markers of CD80, CD83 and CD86. **Song et al also disclose that it has been discovered that the efficiency of immune system stimulation mediated by genetically modifying dendritic cells can be several orders of magnitude greater than that mediated by genetically modified fibroblasts, muscle, and other cell types** (paragraph 39). Song et al further disclose that an expression vector may in addition to directing expression of at least one disease associated antigen, directs the expression of an immunomodulatory factor such as IL-12, IL15, IL-2, beta-interferon among many others (paragraphs 68, 89-90). Song et al also teach that the genetically modifying dendritic cells, including allogeneic cells, are typically administered via parenteral or other traditional direct routes or directly into a specific tissue such as into the tumor in the case of cancer therapy in a mammal (e.g., a human) in need thereof (paragraphs 16-18, 43, 140, 164 and 176).

Song et al did not teach explicitly the use of a Sendai virus vector of a Sendai virus Z strain for genetically modifying immature dendritic cells, including dendritic progenitor cells, even though they disclosed that dendritic cells, including dendritic progenitor cells could be genetically modified by any recombinant negative strand RNA

virus including any paramyxovirus; nor did Song et al teach specifically the use of CD34+ dendritic precursor cells and the step of further culturing the CD34+ precursor cells with GM-CSF and IL-4.

However, at the effective filing date of the present application, Tokusumi et al already disclosed the preparation of **at least a recombinant Sendai virus vector derived from a Sendai virus Z strain to be used for transfer of foreign genes** (see at least the abstract as well as Summary of the Invention; particularly example 1). Tokusumi et al also disclosed that **the Sendai virus vector is useful for gene therapy due to its safety, high gene transfer efficiency and capacity to express a foreign gene in a high level**. Tokusumi et al further disclosed that **they have been focusing their attention on Sendai virus that is not pathogenic towards humans, particularly the Z strain that is especially avirulent; and a laboratory-attenuated Z strain has been isolated, widely used because of its safety and high production titers** (see at least col. 1, line 66 continues to line 31 of col. 2).

Additionally, Jin et al already disclosed successfully a method in which recombinant Sendai virus was in contact and provided **a highly efficient gene transfer into human cord blood CD34+ cells**, including human cord blood HSCs and more immature cord blood progenitor cells (see at least the abstract; page 276, col. 1, last paragraph).

Moreover, Hwu et al also taught at least a method of preparing **recombinant dendritic cells by transforming a hematopoietic stem cell, including CD34+ cells derived from a variety of sources such as cord blood, bone marrow and mobilized**

peripheral blood, with a nucleic acid followed by differentiation of the stem cell into dendritic cells in the presence of GM-CSF, TNF-alpha and optionally together with IL-4 (see at least the abstract; col. 9, lines 29-57; col. 10, line 60 continues to line 13 of col. 11; col. 15, lines 15-46).

Furthermore, Waller et al also taught that progenitors of dendritic cells or immature dendritic cells can be identified in many tissues, such as bone marrow and blood, based on the expression of certain cell surface markers; and that dendritic cell progenitors are typically identified by the expression of one or more of the following markers on its cell surface **CD11c**, CD13, CD14, CD33, **CD34** or CD4 (see at least paragraphs 24-28 and 36).

Accordingly, it would have been obvious and within the scope of skill for an ordinary skilled artisan to modify the teachings of Song et al. by also utilizing a recombinant Sendai virus vector derived from Sendai virus Z strain for genetically modifying immature dendritic cells, including CD11c+ and/or CD34+ dendritic precursor cells derived from bone marrow or cord blood to produce mature dendritic cells expressing at least a recombinant disease associated antigen as encompassed by the instant claims in light of the teachings of Tokusumi et al., Jin et al, Hwu et al and Waller et al as discussed above.

An ordinary skilled artisan would have been motivated to carry out the above modifications because Tokusumi et al already taught that the recombinant Sendai virus vector derived from a Sendai virus Z strain is useful for gene therapy due to its safety, high production titers, well characterized, high gene transfer efficiency and capacity to

express a foreign gene in a high level. Additionally, a highly efficient gene transfer in human cord blood CD34+ cells which are dendritic precursor cells has been successfully achieved and demonstrated by Jin et al. Furthermore, dendritic cell progenitors typically identified at least by the expression of one or more of the following markers on its cell surface such as **CD11c** or **CD34**, derived from a variety of sources such as cord blood, bone marrow and mobilized peripheral blood, have been genetically modified for the preparation of mature dendritic cells expressing desired heterologous proteins/peptides as taught by Hwu et al and Waller et al.

The methods and compositions resulted from the combined teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al are indistinguishable from the methods and compositions as claimed by the present application.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al., coupled with a high level of skill for an ordinary skilled artisan in the relevant art.

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Response to Arguments

Applicants' arguments related to the above modified rejection in the Amendment filed on 1/10/2011 (pages 6-9) have been fully considered but they are respectfully not found persuasive for the reasons discussed below.

Applicants argue basically that none of the cited references describes the use of a vector of a Sendai virus Z strain; and that such a vector could be used successfully to produce mature dendritic cells. Applicants also argue that the Lopez et al reference (JID 187:1126-1136 2003) **which is not applied in the above 103 rejection**, already showed that Sendai Cantell virus is a potent inducer of IFN-I and Sendai 52 virus is a very poor inducer of IFN-I; and Lopez et al also concluded "[t]hese results establish a correlation between type I IFN production by DCs after viral infection and the induction of DC maturation". Based on the conclusion of Lopez et al, Applicants argue that the Sendai virus E72 used by Gary-Gouy et al (Journal of Interferons and Cytokines Research 22:653-659, 2002), **another reference not applied in the above 103 rejection**, which induced IFN-1 at very low level, is therefore also a poor inducer of DC maturation. As such, the prior art describes two Sendai virus strains, 52 and E72, which are poor inducers of DC maturation with only the Sendai virus Cantell was known to induce potent DC maturation. In contrast, Sendai virus Z strain of the present application is shown to be a potent inducer of DC maturation. Therefore, Applicants argue that nothing in the cited references would lead one skilled in the art to use a Sendai virus vector of a Sendai virus Z strain in a method for producing a mature DC, much less have a reasonable expectation that such a method would be successful. Applicants further argue that this is the unexpected result, supported by the examples of the application.

First, Tokusumi et al disclosed explicitly the preparation of **at least a recombinant Sendai virus vector derived from a Sendai virus Z strain to be used**

for transfer of foreign genes (see at least the abstract as well as Summary of the Invention; particularly example 1). Tokusumi et al further disclosed that **they have been focusing their attention on Sendai virus that is not pathogenic towards humans, particularly the Z strain that is especially avirulent; and a laboratory-attenuated Z strain has been isolated, widely used because of its safety and high production titers** (see at least col. 1, line 66 continues to line 31 of col. 2).

Second, the teachings of the Lopez et al reference are incompletely characterized by Applicants. Lopez et al stated "In summary, we have identified a strong correlation between the ability of a virus to trigger DC maturation and the induction of the type I IFN pathway. **Released type 1 IFN is not necessary for virus-induced DC maturation and is not able to induce full maturation by itself** (figure 3). **The up-regulation of costimulatory molecules and MHC class II can be induced separately from the induction of cytokine release**" (page 1134, right col., second full paragraph). This summary and the data shown in the Lopez et al reference do not support Applicants' conclusion that Sendai virus strains, 52 and E72, are poor inducer of DC maturation while the Sendai virus Cantell strain is the only known potent inducer of DC maturation **simply based on the detectable level of induced secreted IFN-1**. Thus, there is no evidence that Sendai virus strain E72 is a poor inducer of DC maturation as argued by Applicants. It is clear however **all of the wild type Sendai virus strains 52, E72 and Cantell are capable of inducing DC maturation; including inactivated Sendai viruses (see at least Table 4 of the Lopez et al reference).**.

Third, with respect to the above 103 rejection an ordinary skilled artisan would have been motivated to select specifically a recombinant Sendai virus vector of a Sendai virus strain Z over other strains because Tokusumi et al already taught clearly that **the recombinant Sendai virus vector derived from a Sendai virus Z strain is useful for gene therapy due to its safety, high production titers, well characterized, high gene transfer efficiency and capacity to express a foreign gene in a high level**. The spontaneous stimulation of immature dendritic cells to mature dendritic cells which are defined as dendritic cells having high expression of CD80, CD83 and CD86 is the "intrinsic property" of a selected Sendai virus. Therefore, this intrinsic property of a recombinant Sendai virus derived from strain Z would occur in the methods and compositions resulted from the combined teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al as set forth in the above 103 rejection; regardless whether any of these inventors are aware of the degree or the extent of spontaneous DC maturation induced by Sendai virus strain Z. This is also an evidence that **the above 103 rejection was not** based on hindsights and/or reconstructed based on the specification of the present application.

Fourth, at the effective filing date of the present application Li et al (J. Virol. 74:6564-6569, 2000; IDS) already demonstrated that **a Sendai virus vector mediated a gene transfer and expression in various types of animal and human cells, including non-dividing cells, with high efficiency; Steinman et al (US 6,300,090) also successfully transfecting proliferating or non-proliferating human dendritic cells (both mature and non-mature cells) with at least a recombinant influenza**

viral vector which is minus-strand RNA viral vector that belongs to the same family as Sendai virus vector (see at least issued claims of US 6,300,090); Kitazato et al (US 2003/0170266) also disclosed the use of F gene deficient Sendai virus, including strain Z for expressing therapeutc gene in dendritic cells (see at least the abstract; paragraphs 5-6 and 84). Last, Curiel-Lewandrowski et al (J. Immunol. 163:174-183, 1999; IDS) also disclosed transfection of immature murine bone marrow-derived dendritic cells with a recombinant adenovirus to enhance the effectiveness of an in vivo DC-based immunotherapy.

Accordingly, there is nothing that is unpredictable or unexpected in transfecting dendritic cells (immature and/or mature dendritic cells) and/or dendritic cell precursors (CD34+ and/or CD11c+ cells) with a recombinant Sendai virus vector derived from strain Z at the effective filing date of the present application based on the combined teachings Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al. coupled with the state of the relevant prior art as discussed above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amended claims 2, 5-7, 10, 15, 20, 25 and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3, 7-9, 12, 15-35 of copending Application No. 11/630,532. ***This is a modified rejection.***

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are directed to a method for producing a mature dendritic cell comprising contacting a Sendai virus vector of a Sendai virus Z strain with a CD11c+ immature dendritic cell or with a CD34+ or CD11c+ precursor cell of a dendritic cell and differentiating the precursor cell into an immature dendritic cell.

Claims 2-3, 7-9, 12, 15-35 of the copending Application No. 11/630,532 are drawn to an anticancer agent comprising a dendritic cell containing a minus strand RNA virus able to replicate its genome, including a Sendai virus encoding an IFN-beta; a method for producing an anticancer agent comprising introducing a minus strand RNA virus into an immature dendritic cell or a precursor thereof and differentiating the precursor into an immature dendritic cell; and a method for suppressing a cancer

comprising the step of administering an immature dendritic cell or a precursor thereof containing a minus strand RNA virus into a subject having a cancer.

The claims of the present application differ from the claims of the copending Application No. 11/630,532 in reciting specifically in all of the claims with a Sendai virus vector of a Sendai virus Z strain.

The claims of the present application can not be considered to be patentably distinct over claims 2-3, 7-9, 12, 15-35 of copending Application No. 11/630,532 when there is a specific disclosed embodiment in the copending Application that teaches that the preferred minus strand RNA viruses of the invention include paramyxoviridae virus such as Sendai virus, including Sendai virus derived from strain Z (see at least page 5, lines 1-36; page 19, lines 26; and examples). Accordingly, the claims of copending Application No. 11/630,532 fall within the scope of claims 2, 5-7, 10, 15, 20, 25 and 30-34 of the present application.

This is because it would have been obvious to an ordinary skilled artisan to modify the claims of the copending Application by also introducing a minus-strand RNA viral vector such as Sendai viral vector derived from strain Z into CD11c+ dendritic cells (both mature and/or immature dendritic cells) or CD11c+ or CD34+ precursors of dendritic cells for the preparation of an anticancer agent and for suppressing cancer in a subject, that support the instant claims. An ordinary skilled artisan would have been motivated to do this because this embodiment is explicitly disclosed or taught in the copending Application No. 11/630,532 as a preferred embodiment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants' argument related to the above rejection in the Amendment filed on 1/10/2011 (page 9) has been fully considered but it is respectfully not found persuasive.

Once again, Applicants argue basically that the provisional rejection should be withdrawn since the present application is an earlier filed application with respect to the copending Application No. 11/630,532 and that if the provisional obviousness-type double patenting rejection is the last remaining rejection in the present case.

It is noted that the provisional obviousness-type double patenting rejection **is not** the last remaining rejection in the present case.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

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/QUANG NGUYEN/

Primary Examiner, Art Unit 1633